IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DEBORAH SHIELDS, Plaintiff, v. **MERCK & CO., INC.,** Defendant.	IN RE FOSAMAX PRODUCT LIABIILTY LITIGATION, MDL 1789 HON. JOHN F. KEENAN Civil Case No. .08-cv-03388 JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Deborah Shields, ("plaintiff"), for her complaint against defendant Merck & co., Inc. ("Merck" or "defendant"), alleges:

1. This is a civil action for damages suffered by plaintiff as a result of ingesting Merck's drug Fosamax which caused plaintiff to suffer from osteomyelitis of the jaw and the sequelae associated thereto.

Parties

2. Plaintiff is a citizen and resident of the state of Ohio, residing in New Concord, Ohio.

3. At all times herein mentioned, defendant was and is a New Jersey corporation, with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100.

4. At all times herein mentioned, defendant did business throughout the United States, including New York and Michigan.

Jurisdiction

5. This court has original jurisdiction over this action under 28 U.S.C. §1332, in that the amount in controversy exceeds seventy-five thousand dollars ($75,000.00) and plaintiff is a citizen of a state which is different from the state where defendant is incorporated and has its principal place of business.

Factual Background

6. Defendant designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax.

7. Fosamax is the brand name of alendronate sodium, which is in a class of prescription drugs called bisphosphonates. Fosamax can be taken orally or intravenously.

8. Fosamax was approved by the United States food and Drug Administration for treatment of osteoporosis.

9. The product literature prepared by Merck and circulated to physicians and pharmacists for use in prescribing the drug contained no warning about osteonecrosis of the jaw or other boney structures.

10. In 2002 or before, defendant knew or should have known that a physician reported that several of his patients who were prescribed Aredia, another bisphosphonate, were diagnosed with osteonecrosis of the jaw and that the physician believed a causal relationship existed between the use of bisphosphonates and osteonecrosis of the jaw.

11. Another group of physicians published a report about patients being diagnosed with osteonecrosis of the jaw after being given Aredia and Zometa, also

bisphosphonates. The report said, "the jaw complications presented in this review have had a major negative effect on the quality of daily life for each of these patients" and determined that "bisphosphonates may be at least partially responsible." Ruggiero, et al., "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004).

12. In September 2004 and May 2005, another manufacturer sent warnings to physicians regarding the risk of osteonecrosis of the jaw with the use of its bisphosphonates, Aredia and Zometa.

13. Merck never issued any warning or changed its product literature to warn of the risk of osteonecrosis of the jaw.

14. Plaintiff was prescribed and took Fosamax.

15. As a result of taking Fosamax, plaintiff developed osteomyelitis of the jaw.

16. As a result of taking Fosamax, plaintiff suffered injuries, including but not limited to:

a. Severe and permanent physical and medical injuries and associated disabilities;

b. Severe past and future pain and suffering;

c. Loss of enjoyment of life;

d. Increased risk of health problems; and

e. Past and future medical care and monitoring.

COUNT I

(Strict product Liability - Design Defect)

Comes now plaintiff and for Count I of her complaint against defendant Merck alleges:

17. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

18. Defendant designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax.

19. Fosamax as designed, manufactured and sold by defendant was defective in design or formulation in that it was unreasonably dangerous because it could cause osteonecrosis of the jaw.

20. Fosamax as designed, manufactured and sold by defendant was defective in design or formulation in that its foreseeable risks exceeded the benefits associated with the design or formulation.

21. Fosamax as designed, manufactured and sold by defendant was defective due to inadequate warnings because defendant knew or should have known that the product created a risk of harm to consumers.

22. Fosamax as designed, manufactured and sold by defendant was defective due to inadequate testing.

23. As the proximate cause and result of the defective condition of Fosamax as designed manufactured and sold by defendant, plaintiff was injured.

COUNT II

(Strict Products Liability/Failure to Warn)

Comes now plaintiff and for Count II of her complaint against defendant Merck alleges:

24. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth in this Count.

25. The Fosamax manufactured and supplied by Merck was unaccompanied by proper and adequate warnings regarding all adverse side effects associated with the use of Fosamax, and the comparative severity and duration of the adverse effects. The warnings given by Merck did not accurately reflect the side effects.

26. Merck failed to perform adequate testing and study Fosamax prior to marketing it or properly analyze and warn based on reports of bisphosphonates causing osteonecrosis of the jaw. Such adequate testing, study or analysis would have shown that Fosamax possessed serious side effects, with respect to which full and proper warnings accurately and fully reflecting symptoms, type of illness, scope and severity should have been given with respect to the use of Fosamax.

27. Merck also failed to act properly on adverse reports it received about Fosamax, and failed to properly study Fosamax pre-market as well as post market and analyze and follow up on reports of bisphosphonates causing osteonecrosis of the jaw.

28. Merck failed to give adequate post-marketing warnings or instructions for the use of Fosamax because after Merck knew or should have known of the risk of injury from Fosamax use, Merck failed to provide adequate warnings to users or

consumers and continued to aggressively promote the product to doctors, hospitals, and directly to consumers.

29. As a direct and proximate result of defendant's failure to warn of the potentially severe side effects of the Fosamax products, as well as the other conduct mentioned in this Count, plaintiff has been damaged.

30. Merck's conduct was done with conscious disregard for safety, justifying an award of punitive damages.

COUNT III

(Negligent Design)

Comes now plaintiff and for Count III of her complaint against defendant Merck alleges:

31. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth in this Count.

32. Defendant Merck designed, produced, manufactured and injected into the stream of commerce, in the regular course of its business, the pharmaceutical drug Fosamax which it knew would be used by plaintiff and others.

33. At the time the Fosamax was manufactured and sold to plaintiff by Merck, it was defective in design and unreasonably dangerous, subjecting users to risks of osteonecrosis of the jaw which exceeded the benefits of the products, and for which other safer products were available.

34. Alternatively, when the Fosamax products were manufactured and sold to plaintiff by defendant, the product was defective in design and formulation, making use of the product more dangerous than other drugs for pain relief.

35. The Fosamax sold to plaintiff reached plaintiff without substantial change. Plaintiff was unaware of the dangerousness of the product until after her use and the development of osteomyelitis of the jaw. Plaintiff ingested the Fosamax without making any changes or alterations.

36. In designing and testing Fosamax, Merck failed to exercise the ordinary care that a careful and prudent drug manufacturer would exercise in the same or similar circumstances.

37. As a direct and proximate result of the negligent design of the Fosamax, plaintiff has been damaged.

38. Merck's conduct was done with conscious disregard for the safety of users of Fosamax, including plaintiff, justifying an award of punitive damages.

COUNT IV

(Negligence, Failure to Warn)

Comes now plaintiff and for Count IV of her complaint against defendant Merck, alleges:

39. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth in this Count.

40. Merck owed a duty to warn of any dangerous defects or side effects; a duty to assure its product did not cause users unreasonable and dangerous risks, reactions, and side effects; and a duty to provide adequate post market surveillance and warnings as it learned of Fosamax's substantial dangers.

41. Merck breached its duty of reasonable care to plaintiff in that Merck failed to:

a. Conduct sufficient testing which, if properly performed, would have shown that Fosamax had serious side effects, including osteonecrosis of the jaw and other serious side effects, and warn users of those risks; and/or

b. Include adequate warnings with Fosamax that would alert users to the potential risks and serious side effects of the drugs; and/or

c. Warn plaintiff that use of Fosamax carried a risk of permanent disability from osteonecrosis of the jaw and other serious side effects; and/or

d. Advise the FDA, the health care industry, plaintiff's physicians, and the public about the adverse reports it had received regarding Fosamax; and/or

e. Other appropriate warnings.

42. Merck should have known that Fosamax caused unreasonably dangerous risks and serious side effects of which the general public would not be aware. Merck nevertheless advertised, marketed and promoted its product knowing there were safer methods and products for pain control.

43. As a direct and proximate result of Merck's negligence and breaches of its duty of reasonable care, plaintiff has been damaged.

COUNT V

(Breach of Express Warranty)

Comes now plaintiff and for Count V of her complaint against defendant Merck alleges:

44. Plaintiff incorporates by reference the preceding allegations as if they were set forth here in full.

45. Defendant expressly warranted, by and through statements made by defendant or its authorized agents, that Fosamax was safe, effective, and fit for its intended use.

46. Plaintiff, and her agents, relied on the skill, judgment and representations of defendant.

47. Fosamax did not conform to defendant's express warranties in that it was not safe and fit for its intended use because it caused serious adverse side effects, including osteonecrosis of the jaw.

48. As the proximate cause and result of defendant's breach of its express warranties, plaintiff was injured.

COUNT VI

(Breach of Implied Warranty)

Comes now plaintiff and for Count VI of her complaint against defendant Merck alleges:

49. Plaintiff incorporates by reference the preceding allegations as if they were set forth here in full.

50. Defendant impliedly warranted to plaintiff, and her agents, that Fosamax was of merchantable quality and was safe and fit for its intended use.

51. Plaintiff and her agents relied on defendant's skill and judgment.

52. Fosamax was not of merchantable quality or safe and fit for its intended use in that it caused serious adverse side effects, including osteonecrosis of the jaw.

53. As the proximate cause and result of defendant's breach of its implied warranties, plaintiff was injured.

COUNT VII

(Negligent Misrepresentation)

Comes now plaintiff and for Count VII of her complaint against Merck, alleges:

54. Plaintiff realleges the allegations in the preceding paragraphs as if fully set out herein.

55. Merck misrepresented to plaintiff and/or her treating physicians the potential serious side effect of osteonecrosis of the jaw based on reports received from physicians, minimized the risk from Fosamax, omitted crucial risk information associated with Fosamax, misrepresented Fosamax safety profile and represented that Fosamax was safe.

56. These representations were made with the actual knowledge of Merck.

57. The representations set forth *supra* were material to plaintiff and/or her treating physician to prescribe and maintain plaintiff's prescription of Fosamax.

58. The representations were made either without knowing of the truth or falsity of the representations or knew or should have known that the representations being made were false and, therefore, defendant failed to exercise reasonable care in making the representations in the scope and course of their employment in marketing Fosamax to individual consumers, plaintiff's treating physicians, hospitals, and other health care providers.

59. Merck intended for plaintiff and/or her treating physicians to rely upon the material misrepresentations to induce them to initially prescribe Fosamax and continue plaintiff on Fosamax.

60. Plaintiff justifiably relied on the representations which were made directly to her or her treating physicians, with Merck knowing that plaintiff was in a limited group who Merck knew would rely upon the information.

61. As a direct result of Merck's negligent misrepresentation, plaintiff incurred personal injuries and actual damages in an amount to be proved at trial. The negligent misrepresentations caused or substantially contributed to cause plaintiffs' damages.

COUNT VIII

(Fraudulent Omission/Concealment)

Comes now plaintiff and for Count VIII of her complaint against defendant Merck alleges:

62. Plaintiff realleges the allegations in the preceding paragraphs as if fully set forth herein.

63. Merck had actual knowledge of reports that Fosamax caused osteonecrosis of the jaw. Despite having knowledge of this side effect of Fosamax, Merck actively concealed and omitted to disclose those effects when marketing Fosamax to doctors, health care providers, and to the general public through direct advertisements.

64. At the time these omissions were made, Merck had knowledge of the substantial and significant risks that Fosamax could cause osteonecrosis of the jaw.

65. Merck omitted to inform plaintiff of the true osteonecrosis of the jaw risks of Fosamax as well as the other adverse health effects of Fosamax. Merck further downplayed the results of various reports showing the risks of osteonecrosis of the jaw from Fosamax as well as other side effects of Fosamax. It also withheld adverse reports or gave incorrect information about the reports it received about the side effects of Fosamax such as osteonecrosis of the jaw.

66. Merck's failure to disclose material facts constituted fraudulent concealment. Merck sanctioned, approved and/or participated in the failure to disclose.

67. Merck had a duty to speak because it had superior knowledge regarding the adverse health effects of Fosamax as set forth herein.

68. The information not disclosed by Merck was unavailable to plaintiff and/or her treating health care professionals. Merck knew the information was unavailable yet approved and participated in instructing its agents, servants and employees to not disclose this information in order to promote the sales of Fosamax over other bisphosphonates.

69. Plaintiff was diligent in attempting to seek the information by consulting with her physicians.

70. The information not disclosed by Merck was not within the reasonable reach of plaintiff and/or her treating physicians and was not discoverable by plaintiff and/or her treating physicians in the exercise of reasonable care.

71. The non-disclosed information was material, Merck knew it was not disclosing complete information and intended that plaintiff and/or her treating

physicians act upon the non-disclosed information in the manner reasonably contemplated.

72. Plaintiff and/or her treating physician was ignorant as to the undisclosed information and had a right to rely on full disclosure.

73. If plaintiff and/or her treating physicians had known the complete information, they would not have prescribed and/or plaintiff would not have taken Fosamax.

74. Merck's non-disclosure of information was outrageous due to their evil motive or reckless indifference to the rights of plaintiff, justifying an award of punitive damages.

WHEREFORE, plaintiff demands judgment in her favor and against defendant Merck for:

A. A fair and just amount of actual damages in an amount to be proved at trial in excess of $75,000:

B. Costs of suit;

C. Pre-judgment and post-judgment interest;

D. Punitive damages in a fair and reasonable amount to punish and deter Merck and others from engaging in the wrongful conduct; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

THE LOWE LAW FIRM

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